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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr.
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SUBJECT: Comments on the Discussion Draft "Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Use" (Docket No. 97N-0217)

FROM: Roy P. E. Yanong, V.M.D., Veterinarian, Tropical Aquaculture Laboratory, University of Florida, 1408 24th St. SE, Ruskin, FL 33570.

The changes proposed by the CVM are a breath of fresh air! I would personally like to thank Linda Wilmot and the rest of the ADAA Minor Use/Minor Species Working Group as well as everyone else involved for all their thoughtful work.

Having worked as an ornamental fish veterinarian in the private sector for four and one half years before taking my present position as a research and extension veterinarian for the ornamental fish industry here in Florida, I am well aware of the frustration of ornamental fish producers and fish health specialists (including myself) caused by the present system, especially in light of the fact that our animals are NOT food animals. In fact, one of the major thrusts of the Tropical Aquaculture Laboratory will be pharmacological research, since this has been identified by many producers as an important component of proper fish health management. The following comments are intended to address some of the questions brought up in the above mentioned document:

A. 1. The proposed modifications of extralabel provisions and suggested sunset period will definitely provide relief, but only if the approval process is changed for minor use/species as outlined in the discussion draft. Also, since use of medicated feeds by aquaculturists is perhaps the most cost effective method of treatment of many infectious diseases, this extralabel use is extremely necessary.
A. 2. The proposed modifications should be extended to include reproductive hormones. Several hormones are used regularly for induced spawning of fish. In addition, methyltestosterone for sex reversal and expression of male phenotype helps to increase the producer's economic return, since male fish are often more desirable. And once again, it is important to remember these animals are not food fish.

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B. 1. One of the biggest problems caused by this lack of approved drugs is questions of drug purity/consistency. The suggested strategies should be helpful in removing existing direct regulatory disincentives, but only if enforcement occurs. However, once again, the approval process itself must be changed in order to complement synergistically the suggested strategies.

C. 1.In the case of ornamental fish, the proposed model program may provide a useful supplement if species grouping is allowed, if funding opportunities are increased, and if incentives exist for a pharmaceutical sponsor.
C.2. The proposed database would be very useful to parties interested in furthering the approval of minor use products. With regards to aquaculture, each of the affected industries can designate a point person or group to submit literature and/or research to a central coordinator for minor species. Additionally, links to other countries should be pursued, as discussed in the Harmonization section.

D.1. Tax credits to producers who participate in minor species clinical field trials sounds like a good incentive.

F. 1.YES, a statutory designation of "minor use animal drug" similar to the statutory designation of "human orphan drug" would be VERY useful. As mentioned in the Discussion Draft, this would accelerate the approval process by providing necessary and numerous incentives including grants, tax credits, protocol assistance, and prolonged periods of marketing exclusivity.

G. 1. Yes, the proposed constraints upon conditional approval for minor uses involving non-food animals would provide sufficient consumer protection, provided the consumer was made aware of the process. I will leave it to the companies to discuss whether incentives are adequate. And yes, the proposed process should be restricted to minor uses involving non-food animals, due to the questions of residues in food animals.

H. 1.The use of an Expert Review Panel (ERP) for minor uses involving non-food animals is an excellent idea, since clinical experience and an intimate understanding of a particular industry or minor species are extremely valuable assets. Animal caretakers will find drugs approved under the proposed alternate standard acceptable, as long as they are informed. Animal caretakers want healthy animals, and the right ERP for each group will help guarantee that.
2. Yes, affected industries including the ornamental fish industry in Florida do have the needed expertise and will be willing to fund the expert review panels.
3. Yes, the process should be restricted to minor uses involving non-food animals.

I. International harmonization is an excellent way of reducing costs for all industries involved as well as providing incentives to private companies for development. Non-governmental input will aid in equivalency determinations. It is too early to tell, but most likely there will be some compromises between our own approval processes and standards and those of the international community. Equivalency determination will help to resolve some of these issues, but may not be enough for some veterinary drugs and biologics.

Thank you very much for giving me this opportunity to provide input. Hopefully my comments have been helpful. The Discussion Draft is insightful and provides the framework for some badly needed change. I hope many of the proposed changes do make

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